Version: November 2019

KENYA
YELLOW FEVER DIAGNOSTICS REQUEST FORM

This template is for countries requesting Gavi support for procurement of yellow fever diagnostic reagents, supplies, and equipment under the Gavi Board-approved Yellow Fever Diagnostics initiative. The following are mandatory requirements to be submitted alongside this request form:

- Signatures required to endorse this request before submission to Gavi: i) Minister of Health, ii) Director of national yellow fever laboratory, and iii) Director of Finance for Ministry of Health. The signature of the Minister of Finance (or their delegated authorities) is recommended but not required.
- The Coordination Forum (ICC, HSCC or equivalent body) is recommended but not required to endorse this request before submission to Gavi. This can be done also through the ICC/HSCC endorsement of the Joint Appraisal (JA) and should be reflected in ICC/HSCC minutes.

Yellow fever diagnostic procurement support is provided to allow more timely, reliable identification and laboratory confirmation of yellow fever cases for more rapid containment of outbreaks and better prioritisation of preventive yellow fever vaccination efforts. Specifically, this support is intended to assist countries' efforts to follow World Health Organization (WHO) recommendations when conducting yellow fever diagnostic tests on all samples received from suspected yellow fever cases. The support is only available to Gavi-eligible countries in Africa that are classified as "high-risk" for yellow fever by WHO under the Eliminate Yellow Fever Epidemics (EYE) strategy[1]. The countries that currently meet those criteria are listed in the **Yellow Fever Diagnostics Support Guidelines**.

The request will be reviewed by members of the Independent Review Committee (IRC) who will make a recommendation to Gavi[2]. Following the independent review there will be a clarification period (30 working days) for countries to respond to any 'issues to be addressed' ahead of final Gavi approval and disbursement.

Submit this request form and the aforementioned requirements to: proposals@gavi.org

Countries requesting Gavi support for the introduction of yellow fever vaccine into the routine immunisation schedule or yellow fever preventive mass campaigns should consult the Application guidelines (section 5.3.8) for more information on the process and requirements. Countries requesting Gavi support for rapid outbreak response for yellow fever (via the International Coordinating Group (ICG)), should consult the yellow fever Application guidelines in the ICG site.

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[1] *The list of Gavi-eligible countries is provided in **Annex 1 Yellow Fever Diagnostics Guidelines**. For the full list of WHO classification, see 'World Health Organization. Eliminate Yellow Fever Epidemics (EYE): A Global Strategy, 2017-2026. Wkly Epidemiol Rec 2017;92:193-204."*

[2] *The requests for consumable reagents and supplies will be reviewed separately from requests for equipment, so support for requested consumables may be recommended even if support for requested equipment is not recommended.*

Gavi Grant Terms and Conditions

Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

GAVI GRANT APPLICATION TERMS AND CONDITIONS

SUPPLIES AND EQUIPMENT USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all material provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All decisions for the supply application are made at the discretion of Gavi and are subject to IRC processes and the availability of funds.

AMENDMENT TO THE APPLICATION

The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

COMPLIANCE WITH GAVI POLICIES

The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi's official website and/or sent to the Country.

ARBITRATION

Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

Gavi will not be liable to the country for any claim or loss relating to the programme(s) described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its application.

REPORTING

The Country's national yellow fever laboratory will report information on yellow fever testing activity and performance as requested by the WHO yellow fever laboratory network in a timely and accurate manner, including on the number of samples received and tested, the results of that testing, the timeliness of the overall testing process and the different steps of that process, and problems encountered with performing yellow fever testing. To simplify reporting and avoid duplication, Gavi will be relying on information from WHO to inform future decisions on whether to renew support for procurement of yellow fever reagents, supplies, and equipment to individual countries.

1. Review and update country information

1.1. Country profile

1.1.1. Country profile

Eligibility for Gavi support

Yes

Date of Partnership Framework Agreement with Gavi

20th January 2020

1.1.2. National customs regulations

Please describe local customs regulations that are instrumental for the delivery of imported laboratory supplies and equipment.

Imported laboratory supplies and equipment attract duties and levies of the Kenya Revenue authority customs department. Waivers of these duties and levies are only exempt by the Cabinet Secretary for national Treasury. Request for waivers originated from KEMRI have to be forwarded to the Cabinet Secretary through the Ministry of Health. This process requires a turnaround time of about 3 months; thus prior availability of documentation for importation and waybill numbers for shipments as well as donation certificates requires to be in country. For reagents and antibiotics clearance by the Pharmacy and Poisons Board is a requirement.

Please describe requirements for pre-delivery inspection of imported goods that are instrumental for the delivery of laboratory supplies and equipment.

Importation of laboratory supplies and equipment have to undergo pre-inspection certification by agencies appointed by the Kenya revenue authority. Pre-inspection is mandatory before goods are shipped to the country.

Please describe any special documentation requirements that are instrumental for the delivery of imported laboratory supplies and equipment.

Pre inspection certificates as described, certificates of origin, donation certificates and shipping documents containing detailed packing lists.

1.1.3. National Regulatory Agency

Please provide information on the National Regulatory Agency in the country, including status (e.g., whether it is WHO-certified).

The Pharmacy and Poisons Board. It is responsible for the implementation of the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating drugs in force in Kenya

Please identify at least one point of contact with phone number and e-mail address at the National Regulatory Agency. UNICEF will help work with regulatory processes where relevant and may need to communicate licensing requirements to laboratory supply manufacturers.

Dr. Allan Wambua

Tel: +254711345902
Email: enquiries@pharmacyboardkenya.org

2. Yellow fever laboratory supplies and equipment

2.1. Number of samples from suspected yellow fever cases expected to be tested for which supplies will be needed

Number of samples received for testing in 2016	10
- Yellow fever outbreak in 2016?	Yes ☒ No ☐
Number of samples received for testing in 2017	4
- Yellow fever outbreak in 2017?	Yes ☐ No ☒
Number of samples received for testing in 2018	2
- Yellow fever outbreak in 2018?	Yes ☐ No ☒
Number of samples expected to undergo ELISA testing over a 12-month period[3]	>50.
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	10
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	4
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	2
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes ☒ No ☐
- If yes, what type of PCR machine is used?	ABI 7500 real time PCR system

[3] *Number of samples expected to undergo ELISA testing over a 12-month period may be estimated to be equivalent to the largest number of samples received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples were received for testing in 2017 than in 2016 or 2018, the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2017. If an outbreak occurred in 2017 and more samples were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2018. Alternative approaches can be used if justification is provided.*

- If no, please describe any plans for starting testing for yellow with PCR in the next 12 months, including description of PCR testing already being done for other viruses	Not applicable
Number of samples expected to undergo PCR testing over a 12-month period[4]	>50. We intend to test at least 50 samples per year to meet the minimum requirements of the number of samples that need to be tested in the laboratory. In the event of any outbreak, we expect the numbers to be higher

2.2. Equipment

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an enzyme-linked immunosorbent assay (**ELISA**) **reader** for yellow fever testing? Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	Prior to 2018, the laboratory was not able to test 50 samples. However, after the initial GAVI assessment in 2018, the laboratory tested 50 samples in 2019 and these was reported in the weekly YF testing reports to WHO. The laboratory does require an ELISA reader exclusively for Yellow Fever testing. In the current setup the reader is shared. At the time of filling in this application, the current reader is unreliable due to software issues.
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	The institute has inhouse engineers and maintenance personnel who are experienced with the installation process having installed similar machines in various departments. For operation and day to day maintenance, the current laboratory personnel are familiar with the various aspects of operating ELISA readers to ensure that equipment is used within its scope and ELISA data collected and interpreted appropriately. In addition, any time a new equipment is introduced SOPS are drafted and all lab personnel trained on various aspects of the new equipment.

[4] *If capacity to test for yellow fever with PCR is available, the number of samples expected to undergo PCR testing over a 12-month period may be estimated to be equivalent to the largest number of samples collected ≤10 days after onset of illness and received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples collected ≤10 days after onset of illness were received for testing in 2017 than in 2016 or 2018, the number of tests expected to be run over a 12-month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2017. If an outbreak occurred in 2017 and more samples collected ≤10 days after onset of illness were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12 month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2018. Alternative approaches can be used if justification is provided.*

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an **ELISA washer** for yellow fever testing?	Yes ☒	No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	The lab requires a dedicated washer specifically for Yellow Fever Work. In the current set up, the washer is used for various ELISA protocols. In addition the current one washes one strip at a time which is slow in an event of a outbreak.
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	Availability of inhouse engineers and maintenance personnel as described above for installation and servicing. In addition, previous experience in the use of ELISA washers by the current personnel ensures that equipment is used within its scope and that the washer is used and maintained appropriately after each wash to avoid clogging. The current personnel are well versed with feeding in the required wash cycle programs for Yellow fever ELISAs.

Does your laboratory receive at least 50 samples a year for yellow fever testing collected no more than 10 days after patients' onset of illness and need a **PCR machine** for yellow fever testing?	Yes ☒	No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	The laboratory requires a dedicated PCR machine specifically for Yellow Fever Work. In the current set up, the PCR machine are used for various tests and are overworked. In the event of a breakdown or maintenance issue due to long hours of use, delays may be experienced in critical times when urgent Yellow Fever samples need to be tested.
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	We have ABI representatives in Nairobi who avail engineers to facilitate the installation and calibration of PCR machines. Staff members are familiar with operating ABI 7500 and collecting and interpreting data from it. Equipment use and maintenance SOPs are also available.

Does your laboratory need a **biosafety cabinet**?	Yes ☒	No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	The laboratory requires a dedicated biosafety cabinet specifically for Yellow Fever Work. In the current set up, the biosafety cabinet is also used to handle other arboviruses. This provides opportunities for potential cross contamination and delays in sample processing especially when one has to wait for other non-Yellow Fever samples to be processed first
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	We have institute engineers trained in biosafety cabinet installation, servicing and certification. They have the necessary credentials and equipment to undertake these tasks. Staff members are versed with aspects of biosafety cabinet use, daily maintenance and SOPS are available to guide this for consistency. Each cabinet will have a daily use and maintenance chart that is audited at the end of every month to ensure that the equipment is used appropriately. The institute has a backup generator that usually mitigates any power blackouts in 1-2minutes.

2.3. Logistics

2.3.1. Supply delivery

What is the address and, if available, geocoordinates of the national public health yellow fever reference laboratory that is the ultimate destination for yellow fever laboratory supplies and equipment?

The address is:
Arbovirus/Viral Haemorrhagic Fever laboratory
Center for Virus Research, Kenya Medical Research Institute
Off Mbagathi Way
P.O Box 54628-00200
Nairobi, Kenya

What is the Port of Entry closest to the national public health yellow fever reference laboratory?
Jomo Kenyatta International Airport, Nairobi

How many shipments should the needed supplies be spread across and why?[5]
Twice a year would be adequate. This is to reduce shipment cost and ensure that the allocated reagents are in place where the testing is to occur. This is however dependent on expiry/shelf life of the supplies. Supplies with a long shelf life (1 year) can be shipped as one shipment. For

[5] *Gavi will fund a maximum of three shipments for supplies used in routine yellow fever testing over a 12-month period (additional shipments are possible in response to outbreaks, if feasible). Exact shipment dates, times, and other details to be confirmed with UNICEF Supply Division.*

those with a shorter shelf life, the shipment should be spread out to twice or 3 times year. The consideration here would be to balance shipment costs with potential stock out situations.

To facilitate timely delivery of supplies, laboratory staff will be responsible providing proof of customs clearance and other import authorizations prior to scheduling a shipment with UNICEF Supply Division. What is the laboratory's plan for securing the necessary customs clearance and any other import authorizations?

The plan is to have a list of all requirements that are needed and share them with UNICEF during the planning stage. The lab staff will liase and be in constant communication with UNICEF prior and during any shipment process. All shipments will be pre planned to allow for adequate time to have all the approvals and authorizations in place prior to the dispatch of any shipment. The lab personnel in Kenya will be responsible for obtaining all the import permits that will be required.

We hope the shipments will be smooth but there are chances that the first shipment will be a learning experience but we envision that the subsequent shipments will be more efficient than probably the first one.

Please identify at least one point of contact with phone number and e-mail address at the laboratory. If the application is approved, UNICEF will reach out to that person to discuss delivery of supplies.

Victor Ofula; +254722899066; victor.ofula@usamru-k.org

Konongoi Limbaso; +254722560850, limbaso@gmail.com; skonongoi@kemri.org

2.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details

Yes, the laboratory relies on manual inhouse method of managing its stocks that is prone to human error and does not give a real time picture of stock use and flow. The laboratory does require that at least one staff member be trained on aspects of stock management and be equipped with the appropriate software or any other tools that will assist. Stock management training will also enable the lab to generate real time stock reports that can be shared with GAVI to avoid any stock out situations

2.4. Strategic considerations

2.4.1. Rationale for the request

Briefly describe how yellow fever diagnostic capacity fits into your country's plan for eliminating yellow fever epidemics.

Kenya historically has had Yellow fever outbreaks and borders countries that have had Yellow Fever outbreaks recently. Kenya is also an international commercial and transport hub where Yellow fever can easily be introduced from outbreak areas. Kenya as a country is keen in working towards Yellow fever elimination and being re classified as a low risk area for Yellow Fever. As a crucial component of elimination an enhanced laboratory system is key to enhancing Kenya's diagnostic capacity is key for prompt detection, reporting and response to any suspect cases in line with local and IHR guidelines. The GAVI support for diagnostic capacity is crucial for Kenya to be able to detect cases promptly and accurately to meet its National and International obligations.

2.4.2. Financial sustainability and budgeting of yellow fever laboratory

A cost sharing requirement will eventually be introduced for **yellow fever materials. This cost-sharing will not come into effect through at least the end of 2020. More information will be provided by your Gavi Senior Country Manager (SCM) as it becomes available. **

What is the current year's and, if available, the next year's domestic budget for yellow fever laboratory capacity needs, including yellow fever laboratory supplies and equipment?

At the moment we do not have a dedicated budget for Yellow Fever supplies and equipment. However, in the event of detection of a Yellow fever positive case, funds would be availed from the government to mount response measures including more testing. This is based from experience in responding to other arbovirus threats previously. It is however difficult to assign a monetary figure to such a response at the moment.

2.4.3. Anticipated future changes in yellow fever laboratory capacity

Aside from access to yellow fever diagnostic reagents, supplies, and equipment, does the laboratory expect its capacity to test for yellow fever to change over the next 2 years, e.g., new staff, training, new facility, etc.? If so, how?

We envision that the diagnostic capacities will grow and hope to have a sequencer within the centre by 2022. In addition, the current laboratory is due to be refurbished in 2020 and with the new layout we will be separating the different testing areas to mitigate and cross contamination. We also expect to have new staff members who will be trained in Yellow Fever diagnostics both within the facility and hopefully in a regional Yellow fever training activity

Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information regarding the application.

Name	Position	Phone Number	Email	Organisation
Joel Lutomiah	Deputy director, CVR	+254729747388	Joel.lutomiah@usamru-k.org	CVR/KEMRI
Konongoi Limbaso	Senior Research Scientist	+254722560850	Limbaso@gmail.com skonongoi@gmail.com	CVR/KEMRI
Victor Ofula	Senior Research scientist	+254722899066	Victor.ofula@usamru-k.org	CVR/KEMRI

Comments

Please provide any comments you have about this application and how to improve it

The "Yes" answers in section 2.2 on the question on whether our lab receives at least 50 samples in based on 2019 figures. Prior to 2019, were testing less than 50 samples and this was pointed out during a GAVI assessment in November 2018. We have worked to improve and test over this minimum number and we do expect to continue improving this year and are positive that GAVI will facilitate support the Kenyan laboratory as Kenya does not have any other partner in regard to Yellow Fever diagnostics at the moment.

This is an opportunity for us to forge a partnership with GAVI that will help us meet our national, regional and international obligations.

We are also aware of the need for self-sustainability in future and it is our vision that once the laboratory is enabled to run from GAVI support, efforts in realising self-sustainability will be less strenuous as the laboratory will already be having basic infrastructure for continuity.

Government signature form

The Government of Kenya would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for yellow fever diagnostics (that is, laboratory reagents, supplies and equipment) as outlined in this request form.

The Government of Kenya commits itself to developing national immunisation services, including laboratory testing that helps guide immunisation services, on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of the Minister of Health, the Director of the national yellow fever laboratory, and the Director of Finance for the Ministry of Health or their delegated authorities.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for procuring yellow fever laboratory reagents, supplies, and equipment will be included in future annual budgets of the Ministry of Health, including funds for co-financing of future Gavi-supported procurement of supplies once the details of the Gavi co-financing requirements are available.

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[6]

Minister of Health (or delegated authority)	**Director of national yellow fever laboratory (or delegated authority)**
Name: Su	Name:
Date:	Date:
Signature:	Signature:

Director of Finance for Ministry of Health (or delegated authority)	**Minister of Finance (or delegated authority) (recommended but not required)**
Name:	Name:
Date: 2	Date:
Signature:	Signature:

[6] *In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.*